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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/030,378

11/09/2001

Jeffrey T. Blue

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06/14/2006

MERCK AND CO., INC

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RAHWAY, NJ 07065-0907

EXAMINER

LE, EMILY M

ART UNIT

PAPER NUMBER

1648

DATE MAILED: 06/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action
Before the Filing of an Appeal Brief**

Application No.

10/030,378

Applicant(s)

BLUE, JEFFREY T.

Examiner

Emily Le

Art Unit

1648

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 25 May 2006 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☐ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☒ The Notice of Appeal was filed on 25 May 2006. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
(a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
(b) ☐ They raise the issue of new matter (see NOTE below);
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☒ Applicant's reply has overcome the following rejection(s): See Continuation Sheet.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
The status of the claim(s) is (or will be) as follows:
Claim(s) allowed: _____.
Claim(s) objected to: _____.
Claim(s) rejected: 1-8 and 18-25.
Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). _____
13. ☐ Other: _____.

Emily Le
E. Le
6/10/06

Jeffrey S. Parkin, Ph.D.
Primary Examiner
Art Unit 1648

Continuation of 5. Applicant's reply has overcome the following rejection(s): The objection of claims 20-21 and 23-24 for a typographical error is withdrawn in view of Applicant's 05/25/2006 submissions. The rejection of claims 21 and 24 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn in view of Applicant's submission.

Continuation of 11. does NOT place the application in condition for allowance because:

Claims 1-8 and 18-25 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential element(s), such omission amounting to a gap between the elements. See MPEP § 2172.01.

In response to the rejection set forth in the record, Applicant submits that the difference in caspase 3 activity provides an indication as to viral stability and potency. Applicant's submission has been considered, however, it is not found persuasive. The claims fail to establish how the difference, quantitatively, translate to a qualitative determination of viral stability and viral potency.

In response to the rejection set forth in the previous office action, Applicant submits that the specification provides data illustrating that a particular incubation time is not critical. Applicant's submission has been considered, however, it is not found persuasive. The claims fail to properly address the delicate nature in which the assay is functional or is capable of rendering a conclusion on viral stability and potency. In the instant, the specification teaches that the linearity of the assay is time dependent.

In response to the rejection set forth in the record, Applicant submits that the skilled artisan can perform the assays under different conditions where there is some variability in the assay results and still obtain meaningful information. Applicant's submission has been considered, however, it is not found persuasive. The issue here is, in the absence of additional teachings that sets forth the conditions or parameters in which the claimed invention should be operated, such as the time period in which infection has taken place, the skilled artisan not be able to obtain a meaningful information in the same context as the claimed invention.

Claims 1-3 and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Banki et al.

In response to the rejection set forth in the record, Applicant submits that Banki et al. fail to teach repeat both steps a) and b). Applicant's submission has been considered, however, it is not found persuasive. In the instant, Banki et al. repeated both steps, wherein the repeated steps with the virus taken from first formulation at two or more time intervals, when Banki et al. measured the activity at different times.

Additionally, in response to the obviousness rejection set forth in the record, Applicant primarily submits that there is no motivation to combine the references cited to support the obviousness rejection. In response to applicant's argument that there is no motivation or suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). Thus, a) claims 4-5 and 18-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Banki et al., as applied to claims 1-3, in view of Duncan et al.; b) claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Banki et al., as applied to claims 1-3, in view of Wu et al.; c) claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Banki et al., as applied to claims 1-3, in view of Goodrich, Jr. et al.; d) claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Banki et al., as applied to claim 18, in view of Esolen et al.; and e) claims 1, 20, 23 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Banki et al., as applied to claim 18, in view of Wu et al. for reason(s) set forth in the record and above.